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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,905	03/04/2004	Yi Li	1488.115000P	3954

28730 7590 01/10/2007
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
ULM, JOHN D	
ART UNIT	PAPER NUMBER
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/791,905	LI ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/16/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Claims 1 to 9 are pending in the instant application.

2) A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 October 2006 has been entered.

3) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5) Claims 1 to 9 stand rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 4 of the office action mailed 25 November of 2005. As stated therein, the instant claims are drawn to an antibody that binds to an epitope contained within a protein identified in the instant specification as "HDGNR10". Beyond the assertion that "HDGNR10" is a putative member of the chemokine receptor family, the instant application does not disclose a **specific** biological role for this protein or its established significance to a particular disease, disorder of physiological process which one would wish to manipulate for a desired clinical effect.

Applicant has traversed this rejection on the premise that the text in paragraphs 0018 and 0094 of "[t]he specification discloses that inhibitors of HDGNR10 (CCR5) may

be used to treat rheumatoid arthritis". As pointed out in the previous office action, this assertion is in direct conflict with the text in paragraph 0016 of the instant specification, which states that "[I]n accordance with still another embodiment of the present invention there are provided processes of administering compounds to a host **which bind to and activate** the receptor polypeptide of the present invention which are useful in stimulating haematopoiesis, wound healing, coagulation, angiogenesis, to treat solid tumors, chronic infections, leukemia, **T-cell mediated auto-immune diseases**, parasitic infections, psoriasis, and to stimulate growth factor activity" (emphasis added). Rheumatoid arthritis is a well known and extensively studied T-cell mediated auto-immune disease. Therefore, the specification as a whole teaches that both inhibitors and activators of HDGNR10 may be used to treat Rheumatoid arthritis, a T-cell mediated auto-immune disease. Such assertions would not be found credible by the skilled immunologist in view of the complete absence of evidence or sound scientific reasoning that both the activation and inhibition of HDGNR10 would have a beneficial effect on an individual suffering from rheumatoid arthritis. Therefore, the instant specification leaves it to that artisan to conduct the additional experimentation that would be needed to establish or reasonably confirm that an agonist of HDGNR10 has any effect on inflammatory processes and if that effect is inflammatory or anti-inflammatory.

Applicant has cited a number of publications describing experiments that were conducted subsequent to the filing of the instant application which show that agonists of the HDGNR10 protein of the instant invention are pro-inflammatory and, therefore, that

the inhibition of these agonists would be expected to be beneficial to the treatment of rheumatoid arthritis. It is noted that these publications do not support Applicant's original assertion that HDGNR10 agonists "are useful in stimulating haematopoiesis, wound healing, coagulation, angiogenesis, to treat solid tumors, chronic infections, leukemia, T-cell mediated auto-immune diseases, parasitic infections, psoriasis, and to stimulate growth factor activity" and that antagonists thereto "are useful in the prevention and/or treatment of allergy, atherogenesis, anaphylaxis, malignancy, chronic and acute inflammation, histamine and IgE-mediated allergic reactions, prostaglandin-independent fever, bone marrow failure, silicosis, sarcoidosis, rheumatoid arthritis, shock and hyper-eosinophilic syndrome",.as alleged in paragraphs 0016 and 0018 of the instant specification.

It is a matter of law that an invention must have a specific and substantial utility "in currently available form", which precludes the need for further research, if that research is needed to establish a specific and substantial utility for the claimed invention (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)), It is clear from the record that Applicant is relying upon research conducted by themselves or others subsequent to the filing of the instant application to establish or reasonably confirm one of the plurality of utilities asserted in the instant application. Because one of ordinary skill would not have found that the evidence presented in the instant application supported the conclusion that a protein of the instant invention had all of the utilities asserted therein, one would have had to engage in that additional experimentation needed to identify which if any of those asserted utilities was actually applicable to a HDGNR10 protein of

the instant invention. Because such additional experimentation was required to establish a specific utility for that protein, it lacked specific and substantial utility "in currently available form" at the time that the instant application was filed.

In response to the assertion that one could not make an agonistic antibody to HDGNR10 protein of the instant invention without knowing the identity of an agonist thereto, Applicant urges that one could have produced antagonistic antibodies to a chemokine receptor without knowing the identity of an agonist thereto and provides an unsubstantiated proposal for how that might be done. Applicant proposes that one could produce antibodies to HDGNR10 and then test those antibodies for beneficial effect in a model system for rheumatoid arthritis. Because there is absolutely no evidence provided by the specification as filed that rheumatoid arthritis would be beneficially effected by the activation or inhibition of HDGNR10, an artisan would have no way of determining if any observed beneficial effect was the consequence of the activation of HDGNR10 by the test antibody, the inhibition of HDGNR10 by that antibody, the action of that antibody on HDGNR10 as an inverse agonist, or the action of that antibody on a structurally related chemokine receptor. Applicant is advised that armchair chemistry is a poor substitute for evidence. There is not a reference of record describing the production of an antagonistic antibody to a chemokine receptor in the absence of the availability of an agonist thereto prior to the filing of the instant application. If Applicant is aware of such a reference they are encouraged to make it of record.

6) Claims 1 to 9 are rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

7) Claim 8 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. As stated in the previous office actions and reiterated above, this claim requires the antibody recited therein to be "an antagonist of the polypeptide of SEQ ID NO:2". An antagonist to a receptor protein, by definition, is an agent that inhibits the activation of that receptor by an agonist. To produce an antibody having the antagonistic activity recited in this claim, one must be able to measure the ability of an antibody to inhibit the agonist activation of a protein having the amino acid sequence of SEQ ID NO:2. The claim is not enabled because neither the instant specification nor the prior art of record describes a process of identifying a compound that inhibits the agonist activation of a chemokine receptor without being able to measure the activity being inhibited.

8) Applicant's arguments filed 16 October of 2006 have been fully considered but they are not persuasive.

9) This is a continuation of applicant's earlier Application No. 10/791,905. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN ULM
PRIMARY EXAMINER
GROUP 1600